

# Rules and Regulations

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## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

#### 7 CFR Part 301

[Docket No. APHIS–2007–0051]

#### Mexican Fruit Fly; Removal of Quarantined Area

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Affirmation of interim rule as final rule.

**SUMMARY:** We are adopting as a final rule, without change, an interim rule that amended the regulations by removing a portion of Webb County, TX, from the list of quarantined areas and by removing restrictions on the interstate movement of regulated articles from that area. The interim rule was necessary to relieve restrictions that were no longer needed to prevent the spread of the Mexican fruit fly into noninfested areas of the United States.

**DATES:** Effective on September 24, 2007, we are adopting as a final rule the interim rule published at 72 FR 34595–34596 on June 25, 2007.

**FOR FURTHER INFORMATION CONTACT:** Mr. Wayne Burnett, Domestic Coordinator, Fruit Fly Exclusion and Detection, PPQ, APHIS, 4700 River Road Unit 36, Riverdale, MD 20737–1231; (301) 734–4387.

#### SUPPLEMENTARY INFORMATION:

##### Background

In an interim rule<sup>1</sup> effective and published in the **Federal Register** on May 18, 2007 (72 FR 27949–27951, Docket No. APHIS–2007–0051), we amended the Mexican fruit fly regulations contained in 7 CFR 301.64

through 301.64–10 (referred to below as the regulations) by quarantining a portion of Webb County, TX, and restricting the interstate movement of regulated articles from the quarantined area. The May 2007 interim rule was necessary to prevent the spread of Mexican fruit fly into noninfested areas of the United States. Comments on the interim rule were required to be received on or before July 17, 2007. We did not receive any comments.

In a second interim rule effective June 18, 2007, and published in the **Federal Register** on June 25, 2007 (72 FR 34595–34596, Docket No. APHIS–2007–0051), we amended the regulations by removing Webb County, TX, from the list of quarantined areas in § 301.64–3(c). That action relieved restrictions that were no longer necessary on the interstate movement of regulated articles from this area. Comments on the interim rule were required to be received on or before August 24, 2007. We did not receive any comments. Therefore, for the reasons given in the interim rule, we are adopting the June 2007 interim rule as a final rule.

This action also affirms the information contained in the interim rule concerning Executive Order 12866 and the Regulatory Flexibility Act, Executive Orders 12372 and 12988, and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived its review under Executive Order 12866.

#### List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

#### PART 301—DOMESTIC QUARANTINE NOTICES

■ Accordingly, we are adopting as a final rule, without change, the interim rule that amended 7 CFR part 301 and that was published at 72 FR 34595–34596 on June 25, 2007.

Done in Washington, DC, this 18th day of September 2007.

**Kevin Shea,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. E7–18762 Filed 9–21–07; 8:45 am]

**BILLING CODE 3410–34–P**

## NUCLEAR REGULATORY COMMISSION

### 10 CFR Parts 32 and 35

RIN 3150–A114

#### Medical Use of Byproduct Material—Minor Corrections and Clarifications

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Direct final rule: Confirmation of effective date.

**SUMMARY:** The Nuclear Regulatory Commission (NRC) is confirming the effective date of October 29, 2007, for the direct final rule that was published in the **Federal Register** on August 13, 2007 (72 FR 45147). This direct final rule amended the NRC's regulations to correct or clarify the rule language in several sections in the regulations that govern specific domestic licenses to manufacture or transfer certain items containing byproduct material and medical use of byproduct material.

**DATES:** The effective date of October 29, 2007 is confirmed for this direct final rule.

**ADDRESSES:** Documents related to this rulemaking, including comments received, may be examined at the NRC Public Document Room, Room O–1F23, 11555 Rockville Pike, Rockville, MD 20852. These same documents are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/NRC/reading-rm/adams.html>. From this site, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1–800–397–4209, 301–415–4737.

**FOR FURTHER INFORMATION CONTACT:** Edward M. Lohr, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415–0253 (e-mail: [eml1@nrc.gov](mailto:eml1@nrc.gov)).

**SUPPLEMENTARY INFORMATION:** On August 13, 2007 (72 FR 45147), the NRC published in the **Federal Register** a direct final rule amending its regulations in 10 CFR Parts 32 and 35 to correct or clarify the rule language in several sections in the regulations that

<sup>1</sup> To view the interim rules, go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS–2007–0051>.

govern specific domestic licenses to manufacture or transfer certain items containing byproduct material and medical use of byproduct material. In the direct final rule, NRC stated that if no significant adverse comments were received, the direct final rule would become final on October 29, 2007. The NRC did not receive any comments that warranted withdrawal of the direct final rule. Therefore, this rule will become effective as scheduled.

Dated at Rockville, Maryland, this 18th day of September, 2007.

For the Nuclear Regulatory Commission.

**Michael T. Lesar,**

*Chief, Rulemaking, Directives and Editing Branch, Division of Administrative Services, Office of Administration.*

[FR Doc. E7-18743 Filed 9-21-07; 8:45 am]

**BILLING CODE 7590-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 610

[Docket No. 2007N-0264]

#### Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Direct final rule; correction.

**SUMMARY:** The Food and Drug Administration is correcting a direct final rule that appeared in the **Federal Register** of August 16, 2007 (72 FR 45883). That document amended the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components and Source Plasma to be more consistent with current practices in the blood industry and to remove unnecessary or outdated requirements. A proposal was published as a companion document to the direct final rule in the same issue of the **Federal Register** (August 16, 2007, 72 FR 45993). Both documents published with a typographical error in the codified section. This document corrects the error in the direct final rule. Elsewhere in this issue of the **Federal Register** we are correcting the error in the proposed rule.

**DATES:** This correction is effective February 19, 2008.

**FOR FURTHER INFORMATION CONTACT:**

*For information regarding this correction:* Joyce Strong, Office of

Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

*For information regarding the direct final rule:* Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:** In FR Doc. E7-15943, appearing on page 45883, in the **Federal Register** of Thursday, August 16, 2007, the following correction is made:

**§ 610.53 [Corrected]**

■ 1. On page 45887, in the amendment to § 610.53 *Dating periods for licensed biological products*, in the table in paragraph (c), “65° C” is corrected to read “-65° C” everywhere it appears.

Dated: September 17, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7-18799 Filed 9-21-07; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA-309F]

#### Designation of Oripavine as a Basic Class of Controlled Substance

**AGENCY:** Drug Enforcement Administration (DEA), Justice.

**ACTION:** Final Rule.

**SUMMARY:** This is a final rule issued by the Drug Enforcement Administration (DEA) designating oripavine (3-*O*-demethylthebaine or 6,7,8,14-tetrahydro-4,5-*alpha*-epoxy-6-methoxy-17-methylmorphinan-3-ol) as a basic class in schedule II of the Controlled Substances Act (CSA). Although oripavine was not previously listed in schedule II of the CSA, it has been controlled in the United States as a derivative of thebaine and, as such, is controlled as a schedule II controlled substance which includes “Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.” Oripavine is a derivative of thebaine, a natural constituent of opium, hence oripavine has been and continues to be, by virtue of the definition of “narcotic drug”, a schedule II controlled substance. International control of oripavine in schedule I of the

1961 Single Convention on Narcotic Drugs (1961 Convention) during the 50th session of the Commission on Narcotic Drugs (CND) in 2007 prompted the DEA to specifically designate oripavine as a basic class of controlled substance in schedule II of the CSA.

**DATES:** Effective September 24, 2007.

**FOR FURTHER INFORMATION CONTACT:**

Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, by e-mail, *ode@dea.usdoj.gov* or by fax, (202) 353-1263.

**SUPPLEMENTARY INFORMATION:**

#### Oripavine Control

Oripavine (3-*O*-demethylthebaine or 6,7,8,14-tetrahydro-4,5-*alpha*-epoxy-6-methoxy-17-methylmorphinan-3-ol) is the international non-proprietary name for a chemical substance which is chemically similar to thebaine. It is a phenanthrene alkaloid contained in various species of the genus *Papaver* and is a major metabolite of thebaine. Although oripavine was not previously listed in schedule II of the CSA, it has been controlled in the United States as a derivative of thebaine and, as such, is controlled under 21 U.S.C. 812(c) Schedule II (a)(1) which includes “Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.” Oripavine is a derivative of thebaine, a natural constituent of opium, hence oripavine has been and continues to be, by virtue of the definition of “narcotic drug”, a schedule II controlled substance (21 U.S.C. 802(17)(A); 21 CFR 1308.12(b)(1)(17)). Oripavine is easily converted into thebaine and thebaine, in turn, is convertible into morphine and morphine derivatives. Both thebaine and morphine are opiates and are controlled under schedule I of the 1961 Single Convention on Narcotic Drugs (1961 Convention): Morphine for its abuse potential and thebaine for its convertibility into morphine derivatives.

#### DEA's Authority To Control Oripavine

This order is prompted by a letter dated June 27, 2007, in which the United States Government was informed by the Secretary-General of the United Nations that oripavine has been added to schedule I of the 1961 Convention. This letter was prompted by a decision at the 50th session of the CND in March 2007 to schedule oripavine under schedule I of the 1961 Convention. As a signatory Member State to the 1961 Convention, the United States is obligated to control oripavine under